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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,219	12/12/2001	Hiroharu Matsuoka	MATSUOKA=18	7465

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EXAMINER

ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,219

Applicant(s)

MATSUOKA ET AL.

Examiner

Binta M. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 22, 26, 27, 28, 29, drawn to the compound of formula I or formula 4, 5, 6 wherein R11 is everything except heterocyclic or -CON(R14)R15 wherein R14 and R15 are all radicals claimed except heterocyclic ring and R14 and R15 do not come together to form a heterocyclic ring, Cy is the phenyl radical of formula 2, and radicals R1-R6, R7, X, R8, R9, R20, R10, R12, and R13 are as defined, and pharmaceutical composition containing the said compound.

Group II, claim(s) 1, 10, 23, 26, 27, 29, drawn to the compound of formula I or formula 4, 5, 6 wherein R11 is everything claimed except heterocyclic or -C(O)N(R14)R15 where R14 and R15 form a heterocyclic ring, Cy is 3-indolyl, and radicals R1-R6, R7, X, R8, R9, R20, R10, R12, and R13 are as defined, and pharmaceutical composition containing the said compound.

Group III, claims 1, 11, 26, 27, 28, 29, drawn to the compound of formula I wherein Cy is C3-7 cycloalkyl provided that when Cy is cyclohexyl, R11 is optionally substituted heterocyclic ring, and when Cy is other than cyclohexyl it is all other moieties claimed, and radicals R1-R6, R7, X, R8, R9, R20, R10, R12, and R13 are as defined, and pharmaceutical composition containing the said compound.

Group III, claim(s) 12, drawn to the compound of formula I, 4, 5, 6 wherein Cy is phenyl and R11 is an optionally substituted heterocyclic ring, and radicals R1-R6, R7, X, R8, R9, R20, R10, R12, and R13 are as defined, and pharmaceutical composition containing the said compound.

Group IV, claim(s) 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 22, 27, 28, 29 drawn to the compound of formula I, 4, 5, 6 wherein Cy is phenyl and R11 is an optionally substituted heterocyclic ring, and radicals R1-R6, R7, X, R8, R9, R20, R10, R12, and R13 are as defined, and pharmaceutical composition containing the said compound.

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Group V, Claim (s) 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 22, 26, 27, 28, 29 drawn to the compound of formula I wherein Cy is 3-indolyl, R11 is C(O)N(R14)R15 where R14 and R15 come together to form a heterocyclic ring

Group VI. Claim 30. drawn to the compound of formula 6 wherein P1 is H, and R11'' are all groups claimed except optionally substituted heterocyclic ring

Group VII. Claim 30 drawn to the compound of formula 6, wherein P1 is a protecting group of amine and R11''' is an optionally substituted ring

Group VIII. Claim 31, drawn to the compound of formula I, wherein Cy is the radical of formula I and all other radicals are as claimed

Group IX. Claim 32, drawn to the compound of formula 8 wherein R11''' is everything claimed except heterocyclic or -CON(R14)R15, and R12', R13, R10, and P3 are all radicals claimed

Groups X. Claim 32, drawn to the compound of formula 8 wherein R11 is -CONR14(R15) wherein R14 and R15 come together to form a heterocyclic ring ,

Groups XI. Claim 34, drawn to the compound of formula (10), wherein R8, R9, R20, and P6 are as claimed

The inventions are distinct, each from the other because of the following reasons:

The species lack a common core

Each Invention Set listed above is directed to or involves the use or making of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over either of

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the other inventions, i.e. they are patentable over each other. Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holdings of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The restrictions of groups I-V are justified above because with the changes in structure, the use of the compounds change. When Cy in formula I is formula 2 and R11 is H for example, the compound of formula I can be used as an antitubercular drug. See compound 627525-94-4, at Ca 140:703. When Cy in formula I is 3-indolyl, compounds with the core of the compound of formula I can be used B3-adrenergic receptor agonists for treatment of obesity, hyperglycemia, increased urinary frequency (pollakiuria), depression, and gallstone. See Ca 140:59659. When Cy in formula I is formula 2 and R11 is a heterocyclic ring, the compound with the basic core structure formula I can be used as an antiviral agent. See Ca 117:27161. When Cy in formula I is 3-indolyl and R11 is heterocyclic ring, the compound with the basic core structure

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formula I can be used as a B lymphocyte stimulator protein binding polypeptides for diagnosis and treatment of immunological disorders. See Ca 136:215417.

Each of Groups VI-XI are distinct and independent, one from the other on the basis of structure defined in the claimed inventions as directed to an intermediate of formula 6, 7, 8, 9, 10 respectively. Absent factual evidence to the contrary, each is a different chemical compound.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claims 1-34 are generic to a plurality of disclosed patentably distinct species comprising Cy, R1-R6, R7, R9, R10, R20, R12, R13. Applicant is required under 35 U.S.C. 372 and 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Roger Browdy on 6/14/04 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1600.


JOSEPH K. McKANE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

BMR
June 14, 2004